

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

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This Document Relates To:

*All Cases*

**PLAINTIFFS' MEMORANDUM IN  
REPLY TO DEFENDANTS'  
OPPOSITION TO PLAINTIFFS'  
MOTION TO EXCLUDE OPINIONS  
AND TESTIMONY OF  
ALEXANDER A. HANNENBERG,  
M.D.**

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## I. INTRODUCTION

Dr. Hannenberg admits a lack of expertise regarding the topics on which he seeks to testify. (Mot. at pp. 5-8)<sup>1</sup> and Defendants' Opposition does nothing to rebut those admissions. Rather, they claim:

Anesthesiologists use patient warming devices, such as the Bair Hugger system, to maintain a patient's body temperature during surgery. Anesthesiologists monitor patients' temperatures throughout a surgical procedure. Dr. Hannenberg is the only anesthesiologist designated as an expert by either side in this litigation, and therefore his opinions will be of particular value to the trier of fact.

(Opp. at p. 1)<sup>2</sup>

The mere fact that anesthesiologists use patient warming devices and Dr. Hannenberg is the only anesthesiologist designated by either side does not qualify him as an expert on the subject matters on which he seeks to opine. Defendants' position is untenable – such a position would allow any person who drives a car to be an expert in automotive safety issues, any web user to be an expert on internet safety, and any gun owner an expert on gun safety. Product use does not equal expertise.

Dr. Hannenberg experience as an anesthesiologist is irrelevant to his opinions regarding the safety of the Bair Hugger because, as even Defendants acknowledge in their brief, “[a]nesthesiologists do not typically follow up with patients after they leave the recovery room” (Opp. at p.6 fn. 3) and Dr. Hannenberg admitted he did not do so

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<sup>1</sup> “Mot. at p. \_\_” refers to Plaintiffs’ Memorandum in Support of Plaintiffs’ Motion to Exclude Opinions and Testimony of Alexander A. Hannenberg, M.D. at D.E. 728.

<sup>2</sup> “Opp at p. \_\_” refers to Defendants’ Memorandum in Opposition to Plaintiffs’ Motion to Exclude the Testimony of Alexander A. Hannenberg, M.D. at D.E. 894.

either. (Mot. at pp. 7, 14). Dr. Hannenberg has *no* personal experience with, or personal knowledge of, the safety or risks of the Bair Hugger causing periprosthetic joint infections, the exact subject on which he seeks to opine. (Mot. at pp. 8-16)

Further, Dr. Hannenberg offers no methodology for his opinions and his proposed expert opinions are little more than personal opinions based on a limited review of selected literature and his use of the Bair Hugger device in his practice. (Mot. at pp. 8-16) Again, Defendants are unable to rebut these contentions, resorting to simply claiming, without citation or quotation to any specific parts of Dr. Hannenberg's report or testimony, that:

Dr. Hannenberg based his expert opinions on more than 20 years of using the Bair Hugger system in his clinical practice; his knowledge, education and training on the benefits of normothermia and risks of hypothermia; the data from his hospital reflecting low infection rates; and review of the vast number of peer-reviewed scientific studies on the benefits of patient warming systems and normothermia.

(Opp. at p. 2)

“An expert who relies upon his personal experience as a basis for his opinion must, nonetheless, be able to point to [the] methods that he applied in reaching that opinion. It is not enough [] for the expert to simply base his conclusions on his thirty-one years of experience.” *Kemp v. Tyson Seafood Group, Inc.*, CIV.5-96-173 JRT/RLE, 2000 WL 1062105 at \*4 (D. Minn. July 19, 2000)(citations omitted). Defendants, however, point to nowhere in Dr. Hannenberg's report or testimony wherein Dr. Hannenberg explains his methodology, any research he has conducted on normothermia, or anywhere where he even states he conducted a literature search, much less how he came to rely on

the specific articles and literature he cites to in his report. Rather, they are only able to generally point to pages three to five of his report, wherein he discusses selected studies, with no indication anywhere on those pages of how he chose those studies to discuss. (Opp. at p. 2) Dr. Hannenberg admitted that he based his opinions solely on selected articles and the opinions of other organizations, *all of which were provided to him by Defendants' counsel*. (Mot. at pp. 8-16). Plaintiffs' extensive discussion of the flaws of Dr. Hannenberg's opinions go un rebutted by Defendants and Plaintiffs' Motion seeking to exclude Dr. Hannenberg's opinions and testimony should be granted under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).<sup>3</sup>

## II. ARGUMENT

### A. Dr. Hannenberg Offers No Methodology For His Opinions

Defendants' erroneously assert that "Dr. Hannenberg employed a sound and valid scientific methodology to reach his conclusions, and his conclusions are reliable." (Opp. at p. 2) Dr. Hannenberg's report is entirely *void* of any description of any scientifically accepted methodology that he used in rendering his opinions and Defendants' Opposition point to none. This lack of methodology was made clear during the deposition of Dr. Hannenberg at which he was given the opportunity to give definitive responses to what

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<sup>3</sup> Defendants also argue in Section I.C that Plaintiffs misrepresent the content of Dr. Hannenberg's report and testimony. Plaintiffs do not. Plaintiffs' citations to Dr. Hannenberg's report and testimony are accurate and support Plaintiffs' interpretations of those texts. Defendants simply choose to interpret such text differently, and in a manner more favorable to them. Rather than engaging in a tit-for-tat discussion of whose interpretation of Dr. Hannenberg's testimony is correct, Plaintiffs respectfully leave that decision to the Court.

materials he had reviewed, considered and/or relied upon, but was unable to give definitive answers. (Dep. 30:5-31:18; 41:24-42:21; 48:9-50:17)<sup>4</sup> Plaintiffs' never suggested that Dr. Hannenberg did not review any literature on the topics at hand but that Dr. Hannenberg cannot provide any sort of valid scientific methodology upon which he relied to determine which studies to review, which studies to disregard, which depositions, parts of depositions, or documents he actually reviewed or relied on, or what research he conducted on the topics he seeks to render his opinions.

During his deposition, Dr. Hannenberg repeatedly failed to demonstrate whether he actually reviewed studies, depositions, or internal documents relevant to his proffered opinions. Dr. Hannenberg testified that he was provided over a hundred documents by 3M's attorneys, but that he did not review all of them, and has no idea how many or which of those he did review. (Dep. 108:25-109:18) Further, Dr. Hannenberg testified that he reviewed depositions, but then stated that "which ones [he reviewed], and which ones [he] relied on the expert reports, [he is] not able to say." (Dep. 15:21-25) Further, as described in detail in Plaintiffs' Motion, there were numerous relevant documents and testimony that Dr. Hannenberg admitted not reviewing. (Mot. at pp. 10-14). This lack of detail as to what Dr. Hannenberg did and did not rely on in coming to his opinions, or how he chose what to review and what not to review, leaves a large a gap between the supposed data that Dr. Hannenberg reviewed and the final opinions that he expressed in

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<sup>4</sup> All references to "Dep. [page]:[line]" are to page and line numbers of the Deposition of Alexander A. Hannenberg taken on August 8, 2017, relevant excerpts of which were attached as Ex. C to the Zimmerman Declaration in of Support Plaintiffs Motion to Exclude Opinions and Testimony of Alexander A. Hannenberg, M.D. at D.E. 729.

his report. “[A] district court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *Smith v. Cangieter*, 462 F.3d 920, 924 (8th Cir. 2006) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

**B. Dr. Hannenberg’s Experience Is Unrelated To The Issues In Dispute In This Matter**

Dr. Hannenberg is a retired anesthesiologist who has not conducted any clinical research in the area of normothermia and has not published any clinical studies or research papers related to thermoregulation or normothermia. (Dep. at 27:20-29:22) He is an expert on maximizing profits in anesthesia, not in methods to maintain normothermia.

Dr. Hannenberg’s use alone of the Bair Hugger is not enough to allow him to opine on matters such as device warnings, safety, and infectious diseases. *See, Kemp*, 2000 WL 1062105 at \*4. As noted above, Dr. Hannenberg admits he has no personal experience or knowledge regarding infection rates using the Bair Hugger, as he never followed up with any of his patients.<sup>5</sup> Further, as detailed in Plaintiffs’ Motion, Dr. Hannenberg admitted that he has done no independent research and published no articles

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<sup>5</sup> Defendants argue in their Opposition that Dr. Hannenberg’s reliance on a purported low .6% infection rate at the Newton Wellesley Hospital is sufficient. (Opp. at p. 5) However, Dr. Hannenberg provides no reliable scientific basis for his claim of a .6% infection rate at Newton Wellesley, citing to no documents in his report to support that claim, and Defendants, in their opposition, point to no source for this information other than the bald statement in his report. Thus, there is no ability for anyone to verify the basis for this claimed rate, or even determine what types of surgeries and infections the rate refers to, much less whether or not it really is better or worse than the national average. Further, Medicare reported that the complication rate of hip/knee surgeries at Newton Wellesley Hospital was over four times of what Dr. Hannenberg reported. (Dep. at 125:22-127:3)

regarding forced-air warming, normothermia, surgical site infections, or infectious diseases. (Mot. at pp. 8-16). Thus, the fact that Dr. Hannenberg may have 20 years of experience using the Bair Hugger is of no import to his expertise to give the opinions he purports to render.

**C. Defendant's Contention that Dr. Hannenberg's Opinions Are Being  
Offered Solely To Critique The Theories And Experts Of Plaintiffs' Is  
Without Merit**

Defendants' incorrectly assert that Dr. Hannenberg is simply a rebuttal expert and his opinions are merely being used to critique the theories and experts of Plaintiffs. (Opp. at p. 3) Defendants then appear to imply that a lower standard applies to such rebuttal experts, and, therefore, that the flaws and failures pointed out by Plaintiffs in Dr. Hannenberg's report can be forgiven. *Id.* Defendants' argument fails both in fact and in law.

Citing to this Court's decision in *Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp. 2d 802, 835 (D.Minn. 2010), Defendants claim that because Dr. Hannenberg is a rebuttal expert, that "his primary purpose in this litigation is to critique the theories and experts of Plaintiffs." (Opp. at p. 3) They then claim that "Dr. Hannenberg's opinions are still admissible even if he offers pure critique, rather than independent theories and conclusions." *Id.* Defendants ignore, however, that it is not the lack of independent theories or conclusions that render Dr. Hannenberg's opinions inadmissible, but rather, his lack of expertise and intellectual rigor in rendering those opinions.

The *Aviva Sports* decision by this Court cited to by Defendants says nothing about lowering the standard for experts who choose to offer solely rebuttal opinions. *Aviva Sports, Inc.*, 829 F. Supp. 2d at 835. Rather, it stands for the proposition that a rebuttal expert may critique the methodology and/or opinions of another expert without having to proffer their own alternative explanations or to explain why those critiques would have produced different results. *Id.* A critique of an opposing expert, however, must still meet the standards for Rule 702. Thus, as this Court found in *Aviva Sports*, the “rebuttal experts sufficiently applied their expertise to the facts and methodologies used by each of Aviva's experts in forming their conclusions.” *Aviva Sports, Inc.*, 829 F. Supp. 2d at 835. The problem here, however, is that Dr. Hannenberg, both lacks the expertise to render opinions on the subjects included in his report and fails to sufficiently apply what expertise he does have in a manner by which Plaintiffs and this Court can test the reliability of his opinions.

Further, as a factual matter, Dr. Hannenberg’s report and proffered testimony go far beyond mere criticisms of Plaintiffs’ experts’ methodologies. In fact, as Defendants’ Opposition admits, Dr. Hannenberg’s report contains the following opinions:

(1) the Bair Hugger system is safe and effective at maintaining normothermia (normal body temperature) and preventing hypothermia, and therefore reduces the risk of surgical site infections; (2) there is a lack of scientifically credible evidence that the Bair Hugger system causes surgical site infections; and (3) labeling for the Bair Hugger system does not require a warning of a risk of infection since no credible scientific evidence establishes that the Bair Hugger system causes infections.

(Opp. at p. 1)



Clearly, Dr. Hannenberg's report and testimony consists of affirmative opinions in support of Defendants' position, not simply critiques of Plaintiffs' experts and their methodologies. Thus, even if *Aviva Sports* stood for the proposition that opinions criticizing an opposing expert are subject to a lower threshold of reliability – and *Aviva Sports* contains no such retooling of the reliability standards – Dr. Hannenberg lacks the expertise, and his report and testimony are insufficiently precise even with respect to criticisms of Plaintiffs' experts, to be admissible.

### III. CONCLUSION

Unreliable and irrelevant information must be kept from the trier of fact because of its inability to assist in factual determinations, its potential to create confusion, and its lack of probative value. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1312 (11th Cir. 1999). For the reasons discussed in Plaintiffs' initial Motion and above, Plaintiffs' respectfully submit that Dr. Hannenberg, his report, and any opinions and testimony that he seeks to offer, should be excluded in their entirety.

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